PATENT
P57672

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF APPEALS AND INTERFERENCES

In re Application of:

YOUNG-TAEK SUL

Appeal № ______________

Serial No.:	10/550,197	Examiner:	LEWIS, RALPH A.
Filed:	21 September 2005	Art Unit:	3732
For:	HELICAL IMPLANT		

APPEAL BRIEF

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313.1450

Sir:

Pursuant to Appellant's Notice of Appeal filed on 12 November 2009, Appellant hereby appeals to the Board of Patent Appeals and Interferences from the final rejection of claims 7, 13 and 19 as set forth in the final Office action mailed on 11 May 2009 (Paper No. 20090511).

Folio: P57672
Date: 4/12/10
I.D.: REB

TABLE OF CONTENTS

I. REAL PARTY IN INTEREST

Pursuant to 37 CFR §41.37(c)(1)(as amended), the real party in interest is:

YOUNG-TAEK SUL
Department of Biomaterials Sciences, Goteborg University,
Box 412, S-405 30 Goteborg, Sweden

the sole inventor of the subject matter defined by the pending claims.

II. RELATED APPEALS AND INTERFERENCES

There are no other appeals and no interferences known to Appellant, Appellant's legal representatives or the assignee which will directly affect, be directly affected by, or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

In compliance with 37 CFR §41.37(c)(1)(*iii*):

Claims 7, 13 and 19 are pending.

Claims 7, 13 and 19 are finally rejected.

Claims 7, 13 and 19 are independent claims.

Claims 1-6, 8-12, 14-18 and 20-24 have been cancelled.

Pursuant to 37 CFR §41.37(c)(1)(*viii*), the claims 7, 13 and 19 are on appeal, as set forth in the accompanying item IX entitled CLAIMS APPENDIX.

IV. STATUS OF AMENDMENTS

Amendment After Final was filed on 11 August 2009, in response to the final Office action (Paper No. 20090511) mailed on 11 May 2009.

No claim was amended in Amendment After Final filed on 11 August 2009.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Pursuant to the current version of 37 CFR §41.37(c)(*v*), a concise explanation of the subject matter of each of independent claims 7, 13 and 19 involved in the appeal, which refers to the specification by page and line number, and to the drawings, by reference characters, is set forth in the following paragraphs.

Claim 7

A helical implant {page 9, line 2, and FIGs. 1 through 5}, may be described as having a core surrounded by helical threads {page 9, line 2, and FIGs. 1 through 4, #10b}, with the inclined flanks {page 9, line 7, and FIGs. 1 through 4, #10a} of said threads bearing a continuum of micro-patterns {page 4, lines 1 through 6}, {page 9, line 3, and FIGs. 1 through 4, #100a, 100b, 100c, 100d} increasing exposed surface area of said helical thread {page 6, lines 3 and 4}, {page 7, lines 14 through 25, and FIGs. 1 through 5}, {page 7, lines 29 through 34}, the micro-patterns comprising one or more {page 6, line 7 (*i.e.*, "the number of patterns") and FIGs. 1 through 4, #100a, 100b, 100c, 100d}, {page 7, lines 20 through 25} recesses and protrusions {page 5, lines 9 through 11, and FIGs. 1 through 4, #100a, 100b, 100c, 100d}, {page 9, lines 2, 3, 6 and 7, and FIGs. 1 through 5, #100a, 100b, 100c, 100d}, and the micro-patterns having continuous and repeated arcuate cross-sectional outlines throughout the entire length {page 7, lines 14 through 20} of the micro-pattern {page 5, lines 22 through 28, and FIGs. 1 through 5}, {page 9, line 2, and FIGs. 1 through 5}, two adjacent said recesses being separated by a distance on an order of 150 μm {page 9, line 12, and FIGs. 1 through 4}.

Claim 13

A helical implant {page 9, line 2, and FIGs. 1 through 5}, may be described as fabricated with a core surrounded by helical threads {page 9, line 2, and FIGs. 1 through 4, #10b} bearing inclined flanks disformed with a continuum of micro-patterns {page 4, lines 1 through 6}, {page 9, line 3, and FIGs. 1 through 4, #100a, 100b, 100c, 100d} increasing exposed surface area {page 6, lines 3 and 4}, {page 7, lines 14 through 25, and FIGs. 1 through 5, #100a, 100b, 100c, 100d}, {page 7, lines 29 through 34} of said implant by extending along said flanks {page 7, lines 14 through 20, and FIGs. 1 through 5, #100a, 100b, 100c, 100d} and around said core, with the micro-patterns comprising one or more recesses and protrusions {page 5, lines 9 through 11, and FIGs. 1 through 4, #100a, 100b, 100c, 100d}, {page 9, lines 2, 3, 6 and 7, and FIGs. 1 through 5, #100a, 100b, 100c, 100d}, and the recesses and protrusions having substantially identical arcuate cross-sectional outlines throughout the entire length {page 7, lines 14 through 20} of the micro-patterns {page 5, lines 22 through 28, and FIGs. 1 through 5}, {page 9, line 2, and FIGs. 1 through 5}, two adjacent said recesses being separated by a distance on an order of 150 μm {page 9, line 12, and FIGs. 1 through 4}.

Claim 19

A helical implant {page 9, line 2, and FIGs. 1 through 5} may be described as fabricated with a cylindrical core {FIGs. 5, 6 and 7}; a screw thread {page 9, line 2, and FIGs. 1 through 4, #10b} surrounding the cylindrical core {page 7, lines 14 through 20, and FIGs. 1 through 5, #100a, 100b, 100c, 100d}, with the screw thread comprising crests, roots and flanks connecting the crests

and the bottoms of the screw thread {page 5, lines 9 through 11, and FIGs. 1 through 4, #100a, 100b, 100c, 100d}, {page 9, lines 2, 3, 6 and 7, and FIGs. 1 through 5, #100a, 100b, 100c, 100d}, and the flanks comprising inclined planes surrounding the cylindrical core {page 7, lines 14 through 20, and FIGs. 1 through 5, #100a, 100b, 100c, 100d}; and

at least one micro-pattern formed on the flanks of the screw thread {page 7, lines 14 through 20, and FIGs. 1 through 5, #100a, 100b, 100c, 100d}, and extending helically in a circumferential direction around the cylindrical core {page 4, lines 1 through 6}, {page 9, line 3, and FIGs. 1 through 4, #100a, 100b, 100c, 100d}, with said micro-pattern comprising at least one groove and at least one ridge having identical arcuate outlines and opened at one side when viewed on any cross sectional plane of the screw thread {page 7, lines 14 through 20} of the micro-patterns {page 5, lines 22 through 28, and FIGs. 1 through 5}, {page 9, line 2, and FIGs. 1 through 5}, and said cross sectional plane containing the longitudinal axis of the cylindrical core {page 7, lines 14 through 20} , the distance between the neighboring micro-patterns being approximately 150 μm {page 9, line 12, and FIGs. 1 through 4}.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Whether claims 7, 13 and 19 are improperly rejected under 35 U.S.C. §103(a) as being unpatentable over the Examiner's proposed combination of Cuilleron (FR 2610512) in view of Hansson et al. (US 5,588,838).

VII. ARGUMENT

Issues raised by Paper No. 20090511

In the final Office action (Paper No. 20090511), the Examiner stated:

- Claims 7, 13 and 19 are rejected under 35 U.S.C. §103(a) as being unpatentable over a proposed combination of Cuilleron (FR 2610512 A) modified in view of Hansson et al., U.S. Patent No. 5,588,838.

Appellant respectfully traverses the Examiner's conclusion-of-law because the evidence introduced into the administrative record does not make a *prima facie* demonstration of obviousness and, on the administrative record, fails to support that conclusion of obviousness under 35 U.S.C. §103(a).

First, as is indicated by a thorough reading of Cuilleron '512, the Examiner's proposed combination fails to teach, or suggest, Appellant's "helical threads." Two observations confirm this omission: first, the perfection of the symmetry in the disposition of the cotyle 1 on both sides of the structures illustrated by Figures 1 and 5, and second, the absence of the adjective "helical" from the specification of Cuilleron '512.

How can the administrative record support the Examiner's finding that Cuilleron '512 teaches any peripheral structure except a series of space-apart concentric rings if Cuilleron '512 itself does not use the adjective "helical?" The use of "threading" in the English language translation is simply that; "threading" is not synonymous with either "helical" or with "helical threading." Threading may be circular, concentrically circular or even axially oriented. The Examiner's proposed combination is silent on the issue of precisely which adjective modifies "threading."

"Helical threads" have been known since the work of Archimedes. Cuilleron '512 knew about "helical threads." Because the implants of Cuilleron '512 are intended for movable anatomical members, such as artificial limbs, the choice of symmetrical radial alignment between the circumferential rings 1c, 2b of Cuilleron '512 was deliberate in order to address the peculiarities and necessity of maintaining the implants within their receiving polyethylene cups, free of sympathetic rotation in response to the corresponding rotation of the attached artificial limb.

It is important to gain an understanding of the Examiner's proposed combination to read the primary reference as teaching an increase in the surface area of contact (*i.e. pour multiplier les surfaces en contact du cotyle (1) dan son logement*) by first inserting the artificial cotyle into a boring without preliminary tapping, and then packing the boring around the artifical cotyle *dans les tissus osseux*. This *tissus osseux* is customarily harvested from either a rib, or more commonly, from the hip of the patient. *Les tissus osseux*, unless it becomes infected, enables a post-operative growth of human bone around the artifical cotyle, thereby anchoring the artifical cotyle within the surrounding bone. The circular projections 1c and 2b, according to Cuilleron '512, better anchor the artificial cotyle 1 (that serves as a socket) and the artificial prostheses 2.

Neither artificial cotyle 1 nor the artificial prostheses 2 of the resulting artificial joint contemplate "helical" threads, despite the written assertion of Paper No. 200900511 that,

> "Cuilleron discloses an implant having a cylindrical core (Figure 5) ***with helical threads*** (2b) for screwing the implant into the intramedullary channel of a prepared femur."

Paper No. 20090511 fails to make a *prima facie* showing of obviousness because the underlying factual basis for the Examiner's ultimate conclusion of obviousness, is false because Cuilleron '512 neither discloses nor suggests Applicant's ***helical threads***. This rejection is therefore unsustainable on the evidence of record.

Second, the Examiner's proposed modification of Cuilleron '512 to incorporate the helically oriented thread 9 of Hansson '838, impermissibly prevents Cuilleron '512 from being used in its intended mode of operation to prevent sympathetic counter-clockwise rotation of the implant in response to rotation of its mating artificial limb. In essence, grafting helical treads onto the primary reference is the antithesis of what is critical in the teachings of the primary reference. Neither artificial cotyle 1 nor the artificial prostheses 2 of the resulting artificial joint contemplate "helical" threads, and the resulting artificial joint is not, on the record before the Board, improved by the presence of helical threads, despite the written assertion of Paper No. 20090511 that,

> "Cuilleron discloses an implant having a cylindrical core (Figure 5) ***with helical threads*** (2b) for screwing the implant into the intramedullary channel of a prepared femur."

Appellant respectfully observes that this assertion from Paper No. 20090511 is inaccurate, and is unsupported by the administrative record.

The Board is respectfully urged to pause and to consider whether the use of Appellant's helical threads in either artificial cotyle 1 or the artificial prostheses 2, as substitutes for symmetrical radially aligned circumferential rings 1c, 2b of Cuilleron '512 would improve, or

detrimentally impair the deliberate effort of Cuilleron '512 to address the peculiarities and necessitates for maintaining these implants free from sympathetic rotation in response to the corresponding rotation of the attached artificial limb? Appellant respectfully submits that the proposed combination, even if that combination would be medically feasible in a human bone, would not be an improvement upon the teachings of Cuilleron '512.

Accordingly, because the proposed combination prevents the Cuilleron '512 from being used in its intended mode of operation, the combination of Cuilleron '512 and Hansson '838 is impermissible under 35 U.S.C. §103(a). This is persuasive evidence of the absence of obviousness in the pending claims.

Third, as best illustrated by the Table printed below, neither the Examiner's proposed combination nor Cuilleron '512 and Hansson '838, whether taken in various combinations or individually, teach Appellant's,

- core surrounded by helical threads,
- with the inclined flanks of said threads bearing a continuum of micro-patterns increasing ... ,
- the micro-patterns comprising one or more recesses and protrusions, and
- the micro-patterns having continuous and repeated arcuate cross-sectional outlines throughout the entire length of the micro-patterns.

Specifically, the threads 9 of Hansson '838 bear neither Appellant's " flanks of ... threads" nor Appellant's " flanks of ... threads bearing a continuum of micro-patterns," and the pitch of the "thread" 9 of Hansson '838 is disclosed as 200 micrometer; consequently, "thread" 9 of Hansson '838 lacks a substrate structure able to support either Appellant's:

> (*a*) "micro-patterns having continuous and repeated arcuate cross-sectional outlines throughout the entire length of the micro-patterns"

or Appellant's,

> (*b*) "micro-patterns having continuous and repeated arcuate cross-sectional outlines throughout the entire length of the micro-patterns, two adjacent said recesses being separated by a distance on an order of 150 μm."

Appellant respectfully submits that the proposed combination, and Hansson '838, teachings nothing more than a series of threads 9 extending around a conically flaring portion 10.

In short, the administrative record establishes that "thread" 9 of Hansson '838 is unadorned with any sort of micro-patterns as defined by Appellant's claims. These micrometer "differences" may not be ignored, either under the requirement of 35 U.S.C. §103(a) that all "differences" be considered, or under the explicit teachings of Cuilleron '512 and Hansson '838 of the crucial anatomical details necessary for the correct manufacture and use of their respective appliances. The fact that some aspects of Cuilleron '512 or Hansson '838 may bear some similarity to the definitions given by Appellant's claims is immaterial to the issue of obviousness, particularly where neither reference teaches Appellant's "micro-patterns having continuous and repeated arcuate

cross-sectional outlines throughout the entire length of the micro-patterns, two adjacent said recesses being separated by a distance on an order of 150 μm." In point-of-fact, the evidence introduced into the administrative record demonstrates that Cuilleron '512 fails to suggest either Appellant's (***a***) "core surrounded by helical threads," or Appellant's (***b***) "core surrounded by helical threads, with the inclined flanks of said threads bearing a continuum of micro-patterns" and that Hansson '838 lacks Appellant's "micro-patterns having continuous and repeated arcuate cross-sectional outlines throughout the entire length of the micro-patterns."

The finding-of-fact set forth in Paper No. 20090511 that Cuilleron '512 "discloses an implant having a cylindrical cord (Figure 5) **with helical threads (2b)**" is fantasy, unsupported by a thorough reading of Cuilleron '512. As noted in the foregoing paragraphs, two observations confirm this omission in Cuilleron '512: first, the perfection of the symmetry in the disposition of the cotyle 1 on both sides of the structures illustrated by Figures 1 and 5, and second, the absence of the adjective "helical" from the specification of Cuilleron '512. How can Cuilleron '512 be said to teach any peripheral structure except series of space-apart concentric rings if Cuilleron '512 itself does not use the adjective "helical?" The use of "threading" in the English language translation is simply that; "threading" is not synonymous with either "helical" or with "helical threading."

These omissions in the administrative record, together with the Examiner's recognition that Cuilleron '512 "does not explicitedly disclose that said micro-patterns have **continuous and repeated arcuate cross-sectional outlines**," and the fact that the "threads" 9 of Hansson '838 can not simultaneously be said to constitute Appellant's (***a***) "helical threads" surrounding a core, or

Appellant's (***b***) "micro-patterns formed on the flanks of helical threads," there is no *prima facie* showing of obviousness.

Appellant respectfully submits that neither Hansson '838" Figures 1, 2 or 3, nor the Examiner' proposed combination teach Appellant's "micro-patterns formed on the flanks of helical threads" because Hansson '838 teaches no adorned "flanks." In other words, Hansson '838, and thus the proposed combination, fails to teach Appellant's "micro-patterns formed on the flanks of helical threads;" and the proposed is an impermissible hindsight reconstruction of the art in the light provided solely Appellant's "micro-patterns formed on the flanks of helical threads" by Appellant's claims.

Given these deficiencies in the evidence introduced into the administrative record, the evidence does not support the Examiner's ultimate conclusion of law of obviousness. Withdrawal of this rejection is therefore, respectfully requested.

Fourth, one of the principal patentable distinctions between the pending claims and the prior art is that the combined prior art fails to teach or suggest Appellant's claims 7, 13 and 19's "*two adjacent recesses being separated by a distance on an order of **150 μm***". This feature is defined by the pending claims, in terms of:

> **Claim 7**, "two adjacent said recesses being separated by a distance on an order of **150 μm**";
>
> **Claim 13**, "two adjacent said recesses being separated by a distance on an order of **150 μm**"; and
>
> **Claim** 19, "the distance between the neighboring micro-patterns being approximately **150 μm**".

It is patentably significant that in Paper No. 20090511, the Examiner explicitly admits that Cuilleron '512 fails to disclose a specific distance between each micro-pattern.

Paper No. 20090511 refers to Hansson '838 which teaches that the distance between adjacent threads may be approximately 0.2 millimeters (*i.e.*, approximately 200 micrometers (μm)), and alleges that,

> "(m)erely providing for similar such spacing (e.g. 150 μm) for the undisclosed spacing of the Cuilleron microthreads in order to promote rapid bone growth into the microthreading would have been obvious to one of ordinary skill in the art."

Additionally, pages 4 and 5 of Paper No. 20090511 state:

> "In the response of October 23,2008 a declaration under 37 CFR1.132 by the inventor concluded that the "150 μm micro-pattern provide optimal site for bone ingrowth" (paragraph 11) and provides evidence in the form of test results that show the ingrowth of bone into micro-patterns of 150 μm. The examiner notes that the declaration fails to provide results for any other spacings and as such fails to provide any basis for arguments that the results are unexpected or have any meaningful distinction over the similarly sized spacing of Hansson which is disclosed as promoting bone growth. Moreover, the mere testing of similarly sized spacings in order to find the most optimal spacing is not of no patentable merit, but rather the result of routine testing obvious to the ordinarily skilled artisan.
>
> Applicant further argues in the response of 12/19/2008 the declaration when taken in context with the originally filed specification the claimed spacing is indeed optimal because it also factors in the desire to maintain the largest possible surface contact area between the implant and the bone. The examiner is not persuaded. One desiring to practice the Cuilleron invention would have to determine the spacing of the microthreads 2c on their own accord since Cuilleron is silent on the issue. Hansson et al teaches that for similar microthreads in a bone implant that thread spacing of around 200 μm is desirable because it provides for rapid bone

> growth. Merely, selecting similar spacing for the Cuilleron microthreading would simply be obvious to the ordinarily skilled artisan as a matter of routine practice."

Appellant respectfully disagrees with the Examiner's assertion because Appellant's "*150 μm spacing between adjacent micro-patterns*" is not obtained by a merely routine testing. Rather, Appellant's "*150 μm spacing*" is carefully selected in order to provide a micro-groove having enough size needed to grow the jaw bone tissue, while maintaining the largest possible surface contact area between the implant and the bone.

The absence of any teaching or suggestions in the evidence introduced into the administrative record of this prosecution history that (***a***) "*spacing between adjacent micro-patterns*" could be determined by routine testing, or (***b***) that "*spacing between adjacent micro-patterns*" is a controllable variable that would be a likely candidate for yielding both (***i***) adequate growth of the jaw bone tissue and (***ii***) maintain the largest possible surface contact area between the implant and the bond. These omissions from the prosecution history may not be ignored in view of the express command of the U.S. Congress set forth in 35 U.S.C. §103(a) that the "differences" between the subject matter sought to be protected by the pending claims and the prior art be identified, and that those differences be weighed against "the subject matter as a whole" before a conclusion-of-law on obviousness be made.

Specifically, as explained in Appellant's Amendment filed on 23 October 2008, Appellant's original specification explicitly discloses that the number of micro-patterns formed on the thread inclines is preferably to be as great as possible, because as the number of the micro-patterns

increased, the contact area of the implant is increased,[1] thereby enhancing the mechanical engaging force between the implant and the bone.[2] In order to increase the number of micro-patterns, the spacing between the micro-patterns should be decreased accordingly. On the other hand, Appellant's original specification also explicitly discloses that the size of the micro-patterns should be 100 μm or more because a micro-groove needed to grow the jaw bone tissue has a minimum size of about 100 μm.[3] Accordingly, Appellant concludes that the micro-patterns should have a size of 150 μm, in order to provide a micro-groove having enough size needed to grow the jaw bone tissue, while maintaining the largest possible surface contact area between the implant and the bone.

On the other hand, neither one of Cuilleron '512 and Hansson '838 has recognized the need for providing a micro-groove both having (*i*) enough size needed to grow the jaw bone tissue, while (*ii*) maintaining the largest possible surface contact area between the implant and the bone. As explicitly admitted by the Examiner, Cuilleron '512 fails to disclose a specific distance between

---

1 Page 6, lines 3-5 of Appellant's original specification reads: "Meanwhile, as **the number of the patterns** is increased, **the contact area** of the implant is also remarkably **increased**, whereas time for machining the patterns is also extended."

2 Page 3, lines 25-30 of Appellant's original specification reads: "The present invention has been made to solve the above problems, and it is an object of the present invention to provide a helical implant, which is formed with a micro-pattern on thread inclines of the helical implant, so that **a contact area and a engaging force between the implant and the jaw bone can be increased**, and so that stress concentration can be restricted, thereby dispersing a physiological load."

3 Page 5, lines 23-25 of Appellant's original specification reads: "... since a micro-groove needed to grow the jaw bone tissue has a minimum size of about 100 Sm, the pattern must be formed to have a size of 100 um or more, preferably 150 m."

each micro-pattern, and Hansson '838 merely discloses that the distance to the adjacent microthread may be 200 μm. Hansson '838's 200 μm is different from Appellant's 150 μm by more than **30 percent**. Table I illustrates these deficiencies in the administrative record:

Present invention	**Cuilleron '512**	**Hansson '838**
a core	an anchoring threading for bone implant	a dental implant having a conically flaring portion 10
surrounded by helical threads		
micro-patterns formed on	**micro threads (1f, 2c)**	**micro-threads 9**
the flanks of helical threads		
	formed on the surface of the threading (1c)	formed on the surface of conically flaring portion 10
with the micro-patterns comprising one or more recesses and protrusions, and		

two adjacent said recesses being separated by a distance on an order of **150 μm.**	micro threads in the dimension of **micrometers**	the distance between adjacent micro-threads 9 may be **200 μm.**

It is doubtful, in view of the foregoing noted deficiency in the evidence present in the administrative record, that there is evidence which would permit an inference that one with ordinary skill in the art will combine Hansson '838 and Cuilleron '512 to reach Appellant's "150 μm spacing."

Paper No. 20090511 reached a further conclusion of law about the obviousness *vel non* of the subject matter defined by Appellant's pending claims, namely that,

> "the mere testing of similarly sized spacings in order to find the most optimal spacing is not of no patentable merit, but rather the result of **routine testing** obvious to the ordinarily skilled artisan",

and

> "Merely, selecting similar spacing for the Cuilleron microthreading would simply be obvious to the ordinarily skilled artisan as a matter of **routine practice**".

This conclusion of law is in not in conformance with the more realistic and earlier statement by Thomas A. Edison, that:

> "Genius is one percent inspiration, ninety-nine percent perspiration."

The laborious and routine testing denigrated by Paper No. 20090511 is, to the contrary, exactly what Thomas Edison said constitutes an invention. To further buttress the Examiner's conclusions

of law, Appellant respectfully submits that in actuality, (*a*) only by unduly tedious and laborious experimentation would an artisan of ordinary skill in the art be able to identify which dimension or spacing would be suitable candidates for consideration for use in Appellant's helical implant, and (*b*) only by further unduly tedious and laborious experimentation would an artisan of ordinary skill in the art be able to obtain,

> "*two adjacent recesses being separated by a distance on an order of **150 µm***"

recited by Appellant's claims 7, 13 and 19. This recognition of the necessity for "***routine testing***" which the Examiner has introduced into the administrative record, is the hallmark of non-obviousness under 35 U.S.C. §103(a).

The Board is therefore, respectfully urged to refuse to sustain the Examiner's conclusion-of-law of obviousness.

SUMMARY

Although the issues before the Board here concern obviousness, Appellant respectfully submits in view of the careful statements written by the Commissioner in *Ex parte Frye* (26 February 2010) about the *standard of review* of questions of anticipation and of obviousness, that when weighing the accuracy of the Examiner's determination-of-law on the issue of obviousness, full consideration must be given to the recent statements by the Director of the U.S.PTO made in reversing the Examiner's final rejection under 35 U.S.C. §102(b) in the *Precedential Opinion*, written in *Ex parte Frye* (26 February 2010),

> "[t]o establish anticipation, every element and limitation of the claimed invention must be found in a single prior art reference, **arranged as in the claim**. *Karsten Mfg. Corp. v. Cleveland Golf Co.*, 242 F.3d 1376, 1383 (Fed. Ciir. 2001)" (Emphasis added)

The question of obviousness is resolved on the basis of underlying factual determinations including (1) the scope and content of the prior art and (2) any differences between the claimed subject matter and the prior art, the conclusion of obviousness before the Board here may not be sustained upon such conclusory findings-of-facts as:

> "Cuilleron discloses an implant having a cylindrical core (Figure 5) ***with helical threads*** (2b) for screwing the implant into the intramedullary channel of a prepared femur."

or,

> "the mere testing of similarly sized spacings in order to find the most optimal spacing is not of no patentable merit, but rather the result of **routine testing** obvious to the ordinarily skilled artisan",

and

> "Merely, selecting similar spacing for the Cuilleron microthreading would simply be obvious to the ordinarily skilled artisan as a matter of **routine practice**".

These erroneous underlying findings-of-fact pervade the Examiner's conclusion of obviousness.

As is noted in the foregoing paragraphs, the absence of *every element* and *every limitation*

found among the teachings of the proposed combination, and the failures noted in the foregoing paragraphs of the proposed combination to teach *every element* and *every limitation* **arranged as in the claim** in conformity with the manner defined by Applicant's claims, and as is suggested by the Director in the *Precedential Opinion*, written in *Ex parte Frye* (26 February 2010), is persuasive evidence of an absence of obviousness *vel non* under 35 U.S.C. §103(a).

Tthe proposed is an impermissible hindsight reconstruction of the art in the light provided solely Appellant's "micro-patterns formed on the flanks of helical threads" by Appellant's claims, that is inimical to the structure, and mode of operation for that structure, taught by Cuilleron '512. This is the antithesis of obviousness, and fatally undermines the Examiner's ultimate conclusion of obviousness.

For these reasons, Appellant believes that the rejection is improper and respectfully requests that the Board refuse to sustain the outstanding rejection of claims.

Respectfully submitted,
/Robert E Bushnell/
Robert E. Bushnell,
Registration No.: 27,774

Customer No. 08439

2029 "K" Street N.W., Suite 600
Washington, D.C. 20006-1004
(202) 408-9040

Folio: P57672
Date: 4/12/10
I.D.: REB

IX. CLAIMS APPENDIX

CLAIMS UNDER APPEAL

Claims 1-6. (Cancelled)

7. (Previously Presented) A helical implant, comprising a core surrounded by helical threads, with the inclined flanks of said threads bearing a continuum of micro-patterns increasing exposed surface area of said helical thread, the micro-patterns comprising one or more recesses and protrusions, and the micro-patterns having continuous and repeated arcuate cross-sectional outlines throughout the entire length of the micro-patterns, two adjacent said recesses being separated by a distance on an order of 150 μm.

Claims 8-12. (Cancelled)

13. (Previously Presented) A helical implant, comprising a core surrounded by helical threads bearing inclined flanks disformed with a continuum of micro-patterns increasing exposed surface area of said implant by extending along said flanks and around said core, with the micro-patterns comprising one or more recesses and protrusions, and the recesses and protrusions having substantially identical arcuate cross-sectional outlines throughout the entire length of the micro-patterns, two adjacent said recesses being separated by a distance on an order of 150 μm.

Claims 14-18. (Cancelled)

19. (Previously Presented) A helical implant, comprising:

a cylindrical core;

a screw thread surrounding the cylindrical core, with the screw thread comprising crests, roots and flanks connecting the crests and the bottoms of the screw thread, and the flanks comprising inclined planes surrounding the cylindrical core; and

at least one micro-pattern formed on the flanks of the screw thread, and extending helically in a circumferential direction around the cylindrical core, with said micro-pattern comprising at least one groove and at least one ridge having identical arcuate outlines and opened at one side when viewed on any cross sectional plane of the screw thread, and said cross sectional plane containing the longitudinal axis of the cylindrical core, the distance between the neighboring micro-patterns being approximately 150 μm.

Claims 20-24. (Cancelled)

IX. CLAIMS APPENDIX

CLAIMS UNDER APPEAL

Claims 1-6. (Cancelled)

7. (Previously Presented) A helical implant, comprising a core surrounded by helical threads, with the inclined flanks of said threads bearing a continuum of micro-patterns increasing exposed surface area of said helical thread, the micro-patterns comprising one or more recesses and protrusions, and the micro-patterns having continuous and repeated arcuate cross-sectional outlines throughout the entire length of the micro-patterns, two adjacent said recesses being separated by a distance on an order of 150 μm.

Claims 8-12. (Cancelled)

13. (Previously Presented) A helical implant, comprising a core surrounded by helical threads bearing inclined flanks disformed with a continuum of micro-patterns increasing exposed surface area of said implant by extending along said flanks and around said core, with the micro-patterns comprising one or more recesses and protrusions, and the recesses and protrusions having substantially identical arcuate cross-sectional outlines throughout the entire length of the micro-patterns, two adjacent said recesses being separated by a distance on an order of 150 μm.

Claims 14-18. (Cancelled)

19. (Previously Presented) A helical implant, comprising:

a cylindrical core;

a screw thread surrounding the cylindrical core, with the screw thread comprising crests, roots and flanks connecting the crests and the bottoms of the screw thread, and the flanks comprising inclined planes surrounding the cylindrical core; and

at least one micro-pattern formed on the flanks of the screw thread, and extending helically in a circumferential direction around the cylindrical core, with said micro-pattern comprising at least one groove and at least one ridge having identical arcuate outlines and opened at one side when viewed on any cross sectional plane of the screw thread, and said cross sectional plane containing the longitudinal axis of the cylindrical core, the distance between the neighboring micro-patterns being approximately 150 μm.

Claims 20-24. (Cancelled)

X. EVIDENCE APPENDIX

None.

XI. RELATED PROCEEDINGS APPENDIX

None.

PATENT
P57672

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

YOUNG-TAEK SUL

Serial No.:	10/550,197	Examiner:	LEWIS, RALPH A.
Filed:	21 September 2005	Art Unit:	3732
For:	HELICAL IMPLANT		

DECLARATION UNDER 37 C.F.R. §1.132

Mail Stop: AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

1. I am YOUNG-TAEK SUL, a citizen of Republic of Korea, having residence at Department of Biomaterials Sciences, Goteborg University, Box 412, S-405 30 Goteborg, SWEDEN, hereby declares as follows:

2. I received my Baccalaureate degree in Dental Surgery from Seoul National University in 1987 and my Doctor degree in implant science from Gothenburg University in 2002.

I am an associate research professor, Department of biomaterials/Handicap Research, Institute for Clinical Science at Shalgrenska Academy, the Gothenburg University, Sweden. I received my Ph.D. degree in Implant Science from the same University in 2002. Young-Taeg Sul is the author and co-author to some 60 peer-reviewed abstracts and papers in international journals. I have made several oral presentations at national- and international conferences. I am frequently involved in referee tasks for several international scientific journals including *Int J Oral Maxillofac Implants, Acta Biomaterials, Biomaterials, J. Electrochemical Society. Electrochemical and Solid-State Letters, and J. Biomedical Materials Research.* My early activity as a dentist focused on clinical research of titanium implants but my research interests over the years have focused on the areas of surface engineering, surface characterization, evaluation methods (experimental and clinical). I have invented surface innovation methods (US Patent 7291178, SE 0104213-4) that are applied to commercial products of the three companies to improve clinical performance of the bone implants. The method is about cations incorporation in the valve metals by the anodic process (So far, it has been found that anions are incorporated). Using the cations, Mg^{2+}, Ca^{2+} incorporated metal surfaces that

reinforced significantly rapid and stronger implant integration to bone. I have proposed a new theory of the implant-to-bone integration, biochemical bonding mechanism.

Peer-reviewed publications (international)

1. Albrektsson T, Johansson C, Lundgren AK, **Sul YT**, Gottlow J. Experimental studies on oxidized implants. A histomorphometrical and biomechanical analysis. Applied Osseointegration Research 2000;1:21-24.
2. **Sul YT**, Johansson CB, Jeong Y, Albrektsson T. The electrochemical oxide growth behaviour on titanium in acid and alkaline electrolytes. Med Eng Phys 2001;23:329-346.
3. **Sul YT**, Johansson CB, Jeong Y, Röser K, Wennerberg A, Albrektsson T. Oxidised implants and their influence on the bone response. J Mater Sci-Mater Med 2001;12:1025-1031.
4. **Sul YT**, Johansson CB, Petronis S, Krozer A, Jeong Y, Wennerberg A, Albrektsson T. Characteristics of the surface oxides on turned and electrochemically oxidized pure titanium implants up to dielectric breakdown: The oxide thickness, micropore configurations, surface roughness, crystal structure and chemical composition. Biomaterials 2002;23:491-501.
5. **Sul YT**, Johansson CB, Jeong Y, Wennerberg A, Albrektsson T. Resonance frequency- and removal torque analysis of implants with turned and anodized surface oxides. Clin Oral Impl Res 2002;13:252-259.
6. **Sul YT**, Johansson CB, Röser K, Albrektsson T. Qualitative and quantitative observations of bone tissue reactions to anodised implants. A histologic, enzyme histochemical and histomorphometric analysis. Biomaterials 2002;23: 1809-1817.
7. **Sul YT**, Johansson CB, Kang YM, Jeon DG, Albrektsson T. Bone reactions to oxidized titanium implants with electrochemically anion S and P incorporation. Clin Implant Dent Relat Res 2002;4:478-487.
8. Jae-Sin Kwon, Won-Bum Kim, Yoon-Mo Kang, **Young-Taeg Sul**. Literature review of implant stability and RFA (Resonance Frequency Analysis). Quintessence Dental Implantology 2002;4:353-359
9. Goui-Seong Yoon, Jae-Sin Kwon ,Dong-Keun Kim, **Young-Taeg Sul**. Assement of implant stability in an osseointegration-simulated model. Quintessence Dental Implantology 2002;4:360-363.
10. Yoon-Mo Kang, Dong-Gyun Jeon, Goui-Seong Yoon, **Young-Taeg Sul**. Quantitative measurements of early osseointegration using RFA (Resonance Frequency Analysis). Quintessence Dental Implantology 2002;4:364-369.
11. **Sul YT**, Johansson CB, Albrektsson T. Oxidized titanium screws coated with calcium ions and their performance in rabbit bone. Int J Oral Maxillofac Implants 2002;17:625-634.
12. Albrektsson T and **Sul YT**. Les implants oxidés perspectives d'avenir?. Réalit és Cliniqlies 2003;13:329-337 (in French).
13. **Sul YT**. The significance of the surface properties of oxidized titanium implant to the bone response: Special emphasis on potential biochemical bonding of oxidized titanium implants. Biomaterials 2003;24:3893-3907.
14. **Sul YT**, Byon E, Jeong Y. Biomechanical Measurements of Calcium-incorporated, Oxidized Implants in Rabbit Bone: Effect of Calcium Surface Chemistry of a Novel Implant. Clin Implant Dent Relat Res 2004;6:101-110.
15. **Sul YT**, Johansson P, Chang BS, Byon E, Jeong Y. Bone response to Mg-incorporated, oxidized implants in rabbit femur: Mechanical interlocking vs Biochemical bonding. J Appl Biomater Biomech 2005;3:18-28.
16. **Sul YT**, Johansson C, Wennerberg A, Cho LR, Jang BS, Albrektsson T. Optimizing surface oxide properties of oxidized implants for reinforcement of osseointegration: Surface chemistry, oxide thickness, porosity, roughness, crystal structure. Int J Oral Maxillofac Implants 2005;20:349-359.
17. **Sul YT**, Johansson C, Byon E, Albrektsson T. The bone response of oxidized bioactive and non-bioactive titanium implants. Biomaterials 2005:26;6720-6730.
18. Byon E, Moon S, Cho SB, Jeong CY, Jeong Y, **Sul YT**. Electrochemical property and apatite formation of metal ion implanted titanium for medical implants. Surface & Coatings Technology 2005;200:1018-1021.
19. **Sul YT**, Jeong Y, Johansson CB, Albrektsson T. Oxidized, bioactive implants are rapidly and strongly

integrated in bone: part 1-experimental implants. Clin Oral Impl Res 2006;17:521-526.

20. **Sul YT**, Johansson C, Albrektsson T. Which surface properties enhance bone response to implants? Comparison of oxidized Mg implant, TiUnite and Osseotite surfaces. Int J Prosthodont 2006;19:319-329.
21. Goransson A, Gretzer C, Johansson A, **Sul YT**, Wennerberg A. Inflammatory response to a titanium surface with potential bioactive properties: an in vitro study. Clin Implant Dent Relat Res. 2006;8:210-217.
22. Arvidsson A, Franke-Stenport V, Andersson M, Kjellin P, **Sul YT**, Wennerberg A. Formation of calcium phosphates on titanium implants with four different bioactive surface preparations. An in vitro study. J Mater Sci Mater Med. 2007;18:1945-1954.
23. Goransson A, Arvidsson A, Currie F, Frank-Stenport V, Kjellin P, Mustafa K, **Sul YT**, Wennerberg A. An in vitro comparison of possibly bioactive titanium implant surfaces. J Biomed Mater Res A. 2008 Apr 10; [Epub ahead of print].
24. **Sul YT**, Kang BS, Johansson B, Um HS, Park CJ, Albrektsson T. The role of surface chemistry and surface topography of osseointegrated titanium implant: strength and rate of osseointegration. J Biomed Mater Res A. 2008 May 9. available online publication.
25. Stenport V, Kjellin P, Andersson M, Currie F, **Sul YT**, Wennerberg A, Arvidsson A. Precipitation of calcium phosphate in the presence of albumin on titanium implants with four different possibly bioactive surface preparations. An in vitro study. J Mater Sci Mater Med 2008;19:3497-3505.
26. **Sul YT**, Byon E, Wennerberg A. Surface characteristics of electrochemically oxidized implants and acid-etched implants: Surface chemistry, morphology, pore configurations, oxide thickness, crystal structure and roughness. Int J Oral Maxillofac Implants 2008;23: 631-640.

Presentations at international conferences (2000-2006)

1. Young-Taeg Sul, Carina Johansson and Tomas Albrektsson. What surface properties determine significant differences of bone response to oxidized Mg-incorporated, TiUnite and Osseotite implants? Regenerate World Congress on Tissue Engineering and Regenerative Medicine, April 25 – 27 and the Society For Biomaterials Annual Meeting , April 26 – 29, Pittsburgh, Pennsylvania, USA, 2006.
2. Young-Taeg Sul, Eungsun Byon, Byung-Soo Kang and Ann Wennerberg. Surface characteristics of surface-engineered titanium implants: Surface chemistry, morphology, pore configuration, oxide thickness, crystal structure and roughness. Regenerate World Congress on Tissue Engineering and Regenerative Medicine, April 25 – 27 and the Society For Biomaterials Annual Meeting , April 26 – 29, Pittsburgh, Pennsylvania, USA, 2006.
3. Young-Taeg Sul, Yongsoo Jeong, Carina Johansson and Tomas Albrektsson. Rate and strength of osseointegration of oxidized and machined, turned titanium implants in rabbit bone for 3 and 6 weeks. Regenerate World Congress on Tissue Engineering and Regenerative Medicine, April 25 – 27 and the Society For Biomaterials Annual Meeting , April 26 – 29, Pittsburgh, Pennsylvania, USA, 2006.
4. Carlsson C, Johansson CB, Holmgren Peterson K and Sul YT. Comparisons of Bone Tissue Formation Around Pure Titanium Implants Using Light- and Fluorescence Microscopically Techniques. European Society for Bioma terials, Nantes, France, Sept. 2006.
5. Carina B Johansson, Young-Taeg Sul and Tomas Albrektsson. Biochemical bonding of biomaterials. Medicinteknikdagarna, 27-28 September, 2005, Stockholm, Sweden.
6. Byon E-SP^{P}, Jeong Y, USul Y-TU. SEM observations of bone to oxidized bioactive implant interface. 20th Annual Meeting of the Academy of Osseointegration, 10-12 March 2005 FL, USA.
7. Chang B-S and Sul YT. Biochemical bonding of Mg-incorporated, oxidized implants in rabbit femur. 20P^{thP} Annual Meeting of the Academy of Osseointegration, 10-12 March 2005 FL, USA.
8. Cho RL and Sul YT. Removal torque measurements of micro-patterned implants in rabbit bone. 20P^{thP} Annual Meeting of the Academy of Osseointegration, 10-12 March 2005 FL, USA.
9. Sul YT. Johansson P, Johansson CB, Byon E, Albrektsson T. Removal torque measurements of Mg-incorporated, oxidized implants in rabbit bone. 7P^{thP} World Biomaterials Congress, 17-21 May 2004 Sydney, Australia.
10. Sul YT. Johansson CB, Albrektsson T. Biomechanical measurements of Ca-incorporated, oxidized implants in rabbit bone. 7P^{thP} World Biomaterials Congress, 17-21 May 2004 Sydney, Australia.
11. Byon E, Sul YT, Jeong Y, Albrektsson T. Pore characteristics and oxide thickness of the surface oxides of the titanium implants electrochemically formed in a mixed electrolyte. 7P^{thP} World Biomaterials Congress, 17-21

May 2004 Sydney, Australia.

12. Chang BS, Byun ES, Kim WB, Sul YT, Albrektsson T. Optimizing surface oxide properties of oxidized implants for reinforcement of osseointegration. 13P^{thP} European Association for Osseointegration, 16-18 Sept 2004 Paris, France.
13. Um HS, Jeong Y, Sul YT, Johansson. SEM study of bone growth on the pore of the oxidized implant. 13P^{thP} European Association for Osseointegration, 16-18 Sept 2004 Paris, France.
14. Sul YT, Cho RL, Johansson C, Albrektsson T. Oxidized, bioactive implants are rapidly and strongly integrated in bone. 13P^{thP} European Association for Osseointegration, 16-18 Sept 2004 Paris, France.
15. Sul YT, Johansson CB and Albrektsson T. Biochemical Bonding vs. Mechanical Interlocking in Osseointegration of Oxidized Implants. 18P^{thP} Annual Meeting of the Academy of Osseointegration, 2003, Boston, USA.
16. Dong-Gyun Jeon, Yoon-Mo Kang, Dong-Keun Kim, In-Sup Kim, Young-Taeg Sul. A comparation between countersink and non-countersink in the mandibular posterior region: A clinical pilot study. 18P^{thP} Annual Meeting of the Academy of Osseointegration, 2003, Boston, USA
17. Won Bum Kim, Kyung Gwan Min, Heung Bin Yim, Yong Geun Park, Young-Taeg Sul. A study of implant stability with variance in the exposed and engaged length of implant fixtures. 18P^{thP} Annual Meeting of the Academy of Osseointegration, 2003, Boston, USA.
18. Young-Taeg Sul and Carina Johansson. Determinant surface properties of oxidized implants for reinforced osseointegration. IADR meeting, 2003, Gothenburg, Sweden
19. Wennerberg A, Sul YT, Condeco J, Rosen B-G, Jeon D-G. Electrochemical characteristics and surface properties of oxidized implants (LouiP^{TMP}). IADR meeting, 2003, Gothenburg, Sweden.
20. YG Pack and YT Sul. An improved initial stability of the titanium implant in bovine bone by altering surgical technique. IADR meeting, 2003, Gothenburg, Sweden.
21. GC Chae and YT Sul. In vitro stiffness measurements of titanium implants. IADR meeting, 2003, Gothenburg, Sweden.
22. KG MinP ^{P}and UYT Sul. Effect of the implant fixture length on RFA measurements in cancellous bone. IADR meeting, 2003, Gothenburg, Sweden.
23. Dong-Gyun Jeon, Young-Taeg Sul, Carina B. Johansson, Tomas Albrektsson. Enhanced osseointegration of sulphated titanium implants. 17P^{thP} Annual Meeting of the Academy of Osseointegration, March 14-16, 2002, Dallas, Texas, USA.
24. Yun-Mo Kang, Young-Taeg Sul, Carina B. Johansson, Tomas Albrektsson. Enhanced osseointegration of phosphated titanium implants. 17P^{thP} Annual Meeting of the Academy of Osseointegration, March 14-16, 2002, Dallas, Texas, USA.
25. Young-Taeg Sul, Carina B. Johansson, Ann Wennerberg, Tomas Albrektsson. Enhanced osseointegration of Ca incorporated titanium implants. 17P^{thP} Annual Meeting of the Academy of Osseointegration, March 14-16, 2002, Dallas, Texas, USA.
26. Jae-Sin Kwon, Goui-Seong Yoon, Dong-Keun Kim, Won-Bum Kim, Young-Taeg Sul. Assessment of implant stability in an osseointegration-simulated model. 17P^{thP} Annual Meeting of the Academy of Osseointegration, March 14-16, 2002, Dallas, Texas, USA.
27. Young-Taeg Sul, Carina B. Johansson, Dongsoo Kim, Yongsoo Jeong, Tomas Albrektsson. Effects of electrochemical parameters on growth behaviour of titanium oxide in acid and alkaline electrolytes. European Society for Biomaterials conference, London, England, Sept. 12-14, 2001.
28. Young-Taeg Sul, Carina B. Johansson, Ann Wennerberg, Yongsoo Jeong , Tomas Albrektsson. Hard tissue reactions to oxidised implants. A biomechanical evaluation using Resonance Frequency Analysis and Removal torque. European Society for Biomaterials conference, London, England, Sept. 12-14, 2001.
29. Young-Taeg Sul, Carina B. Johansson, Kerstin Röser, Tomas Albrektsson. Hard tissue reactions to oxidised implants. An enzyme histochemical and histomorphometric analysis. European Society for Biomaterials conference, London, England, Sept. 12-14, 2001.
30. Young-Taeg Sul, Carina B. Johansson, Yongsoo Jeong, Kerstin Röser, Ann Wennerberg, Tomas Albrektsson. On the bone tissue response to different surface properties of anodised titanium implants. Six World Biomaterials Congress, Kamuela, Hawaii,USA, May 15-20, 2000.
31. Sul YT, Johansson CB, Wennerberg A, Albrektsson T. Hard tissue reactions to anodised implants. Part 1: A

biomechanical evaluation using Resonance Frequency Analysis and Removal torque. Abstract in Medicinska forskningsrådets (MFR) planeringsgrupp i biomaterialforskning, Göteborg University, Göteborg, Sweden, 2000.

32. **Sul YTU**, Johansson CB, Röser K and Albrektsson T. Hard tissue reactions to anodized implants. Part 2: A histologic, enzyme histochemical and histomorphometric analysis. Abstract in Medicinska forskningsrådets (MFR) planeringsgrupp i biomaterialforskning, Gothenburg University, Gothenburg, Sweden, 2000.

3. I have been practiced in this field for approximately 18 years.

4. I am an inventor of the above-referenced application.

5. I declare and submit evidence establishing that a helical implant formed with 150 µm micro-patterns on thread inclines promotes bone mineralization and maturation.

6. FIGS. 1-3 are histomorphomertic and fluorescence microscopic photos showing animal bone growth in 150 µm micro-patterns constructed as embodiments according to the principles of the invention, at the healing time of 6 weeks.

7. In FIG. 1, the 150 μm micro-patterns are formed at the conical 1/3 area of the implant. Fluorescence agents such tetracycline (15mg/kg body weight, Fluka, Buchs, Switzerland), alizarin-complexon (30mg/kg body weight, Fluka, Buchs, Switzerland), calcein blue (30mg/kg body weight, Fluka, Buchs, Switzerland), were injected in the animals at 2, 4 and 6 weeks in order to show the bone growth. FIG. 1 clearly shows the bone growth into the 150 μm micro-patterns at the conical 1/3 thread of the screw implant.

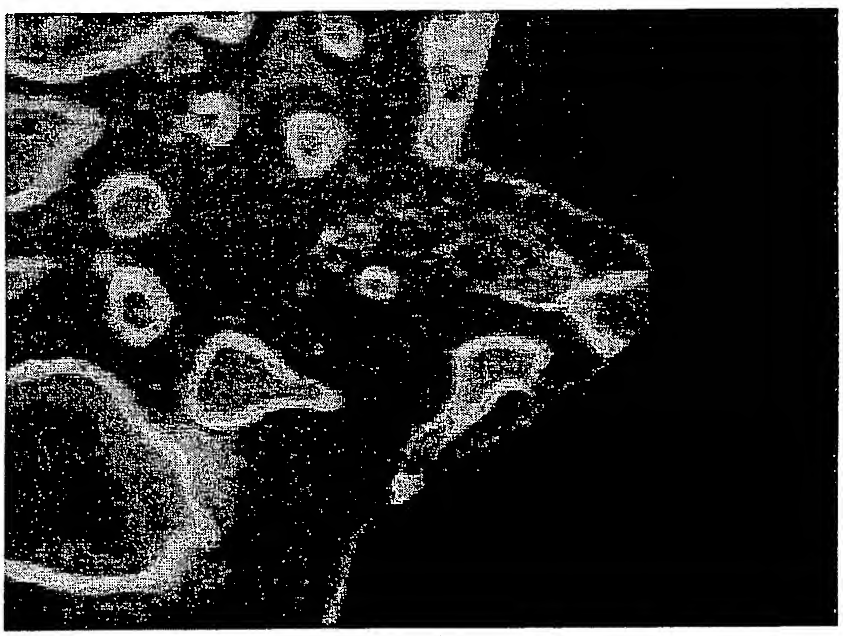

FIG. 1

8. In FIG. 2, the 150 μm microthreads are formed at the middle 1/3 area of the implant. FIG. 2 clearly shows the bone growth into the 150 μm micro-patterns at the middle 1/3 thread of the screw implant.

FIG. 2

9. In FIG. 3, the 150 μm microthreads are formed at the apical 1/3 area of the implant. FIG. 3 clearly shows the bone growth into the 150 μm micro-patterns at the apical 1/3 thread of the screw implant, where the bone tissue and microthread was surrounded with bone marrow tissue.

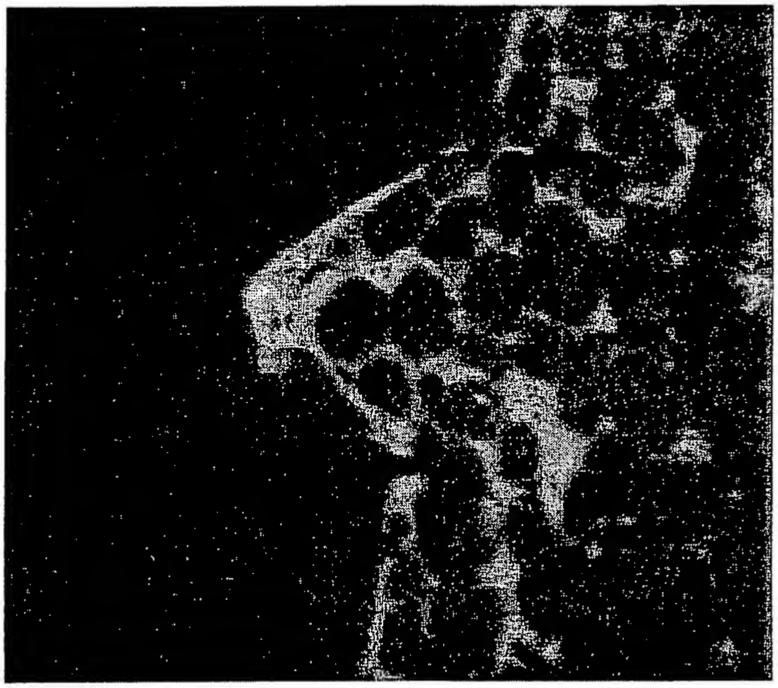

FIG. 3

10. As shown in FIGs 1-3, after the helical implant which is formed with micro-patterns with a distance of 150 μm, is implanted into the animal bone tissue, the bone grew into the thread.

11. The 150 μm micro-pattern provide optimal site for bone ingrowth. Particularly, in a bone system such as a Haversian system in which Haversian canals surround blood vessels, the 150 μm micro-pattern may promote bone mineralization and eventually maturation. As a consequence, the strength and speed of an osseointegration, i.e., direct structural and functional connection between the bone and the surface of the implant, will be increased.

I HEREBY DECLARE that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 U.S. Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

FULL NAME OF FIRST OR SOLE INVENTOR: YOUNG-TAEK SUL Citizenship: Republic or Korea

Inventor's signature: Date: Oct 20. 2008
Residence Address: Department of Biomaterials Sciences, Goteborg University, Box 412, S-405 30 Goteborg, SWEDEN